

Appl. No. 10/731,859
Response dated August 21, 2006
Reply to Office Action of April 19, 2006

AMENDMENT TO THE CLAIMS:

Claim 1. (Currently Amended) A sustained release dosage form, comprising from about 500 mg to about 1000 mg of an insoluble NSAID and an effective amount of a sustained release carrier, said dosage form providing effective blood plasma levels and a dissolution of said NSAID in-vitro when measured by the USP Type II (Paddle) Method, of from about 6 percent by weight of said NSAID released after about 2 hours and a t_{50} after about 12 to about 16 hours.

Claim 2. (Original) The dosage form of claim 1, wherein said sustained release carrier comprises xanthan gum and a cross linking agent.

Claim 3. (Original) The dosage form of claim 2, wherein said crosslinking agent is a galactomannan.

Claim 4. (Original) The dosage form of claim 3, wherein said galactomannan is locust bean gum.

Claim 5. (Original) The dosage form of claim 1, further comprising an inert diluent.

Claim 6. (Original) The dosage form of claim 1, wherein said NSAID is selected from the group consisting of ibuprofen, calcium fenoprofen, naproxen, etodolac, mefenamic acid, tolmetin, and mixtures thereof.

Claim 7. (Original) The dosage form of claim 1, wherein said NSAID is ibuprofen.

Claim 8. (Original) The dosage form of claim 1, which is in the form of a tablet.

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Claim 9. (Original) The dosage form of claim 2, wherein said cross-linking agent comprises a galactomannan gum, an ionizable gel strength enhancing agent, or a combination thereof.

Claim 10. (Currently Amended) A sustained release dosage form, comprising from about 500 mg to about 1000 mg of an insoluble NSAID and an effective amount of a sustained release carrier, said dosage form providing effective blood plasma levels and a dissolution of said NSAID in-vitro when measured by the USP Type II (Paddle) Method, of from about 20 percent by weight of said NSAID released after about 4 hours and a t_{50} after about 12 to about 16 hours.

Claim 11. (Original) The dosage form of claim 10, wherein said sustained release carrier comprises xanthan gum and a crosslinking agent.

Claim 12. (Original) The dosage form of claim 11, wherein said crosslinking agent is a galactomannan.

Claim 13. (Original) The dosage form of claim 12, wherein said galactomannan is locust bean gum.

Claim 14. (Original) The dosage form of claim 11, further comprising an inert diluent.

Claim 15. (Original) The dosage form of claim 10, wherein said NSAID is selected from the group consisting of ibuprofen, calcium fenoprofen, naproxen, etodolac, mefenamic acid, tolmetin, and mixtures thereof.

Claim 16. (Previously Presented) The dosage form of claim 10, wherein the said NSAID is ibuprofen.

Claim 17. (Original) The dosage form of claim 12, wherein said cross-linking agent comprises a galactomannan gum, an ionizable gel strength enhancing agent, or a combination thereof.

Claim 18. (Currently Amended) A sustained release ibuprofen dosage form comprising about 500 mg to about 1000mg ibuprofen; a sustained release coating comprising a hydrophobic material; and a tablet core comprising xanthan gum, wherein from about 1 to about 20 percent by weight of said ibuprofen is coated on said tablet, said dosage form providing effective blood plasma levels and a dissolution of said NSAID ibuprofen in-vitro when measured by the USP Type II (Paddle) Method, of from about 6 percent by weight of said NSAID ibuprofen released after about 2 hours and a t_{50} after about 12 to about 16 hours.

Claim 19. (Currently Amended) An oral sustained release dosage form, comprising a matrix comprising from about 500 to about 1000 mg of ibuprofen and a sustained release carrier comprising about 5 to about 95% xanthan gum and a crosslinking agent comprising locust bean gum; wherein the weight ratio of said ibuprofen to the combined weight of said xanthan gum and said locust bean gum is from about 1:0.06 to about 1:0.4, said dosage form providing effective blood plasma levels of said ibuprofen.

Claim 20. (Currently Amended) The oral sustained release dosage form of claim 19, wherein the weight ratio of said NSAID ibuprofen to the combined weight of said xanthan gum and said locust bean gum is from about 0.08 to about 0.25.

Claims 21. (Previously Presented) The sustained release tablet of claim 19, comprising from about 800 mg to about 1000 mg ibuprofen.

Claim 22. (Currently Amended) A method of preparing an oral sustained release dosage form comprising the steps of wet granulating a mixture of xanthan gum, locust bean gum, an inert diluent and an insoluble ibuprofen in a ratio of xanthan gum to locust bean gum is from about 1:20 to about 20:1 and in a ratio of the total weight of ibuprofen to the combined weight of said xanthan gum and said locust bean gum is from about 1:0.06 to about 1:0.4; and

tableting the resulting granulate into tablets containing from about 500 mg to about 1000 mg of ibuprofen, said dosage form providing effective blood plasma levels of said ibuprofen.

Claim 23. (Currently Amended) A sustained release pharmaceutical excipient for use in oral solid dosage forms, comprising xanthan gum, a galactomannan capable of cross-linking said xanthan gum in the presence of aqueous solutions, and from about 20 to about 35 percent by weight of an inert diluent, said dosage form providing effective blood plasma levels of an NSAID.

Claim 24. (Currently Amended) A sustained release tablet comprising from about 500 mg to about 1000 mg of an insoluble NSAID in a sustained release matrix comprising xanthan gum and locust bean gum, wherein the total weight of said tablet is from about 110 percent to about 140 percent by weight of said insoluble NSAID, said xanthan gum and said locust bean gum comprising from about 7 to about 40 percent by weight of the tablet, said tablet providing effective blood plasma levels of said NSAID.

Claim 25. (Original) The sustained release tablet of claim 24, wherein said NSAID is ibuprofen and the combined weight of said xanthan gum and said locust bean gum is from about 119 percent to about 136 percent of ibuprofen.

Claim 26. (Currently Amended) A method of retarding the release of ibuprofen from a sustained release ibuprofen tablet containing xanthan gum when the tablet is exposed to an aqueous environment comprising replacing from about 5 to about 95 percent by weight of the xanthan gum in the sustained release ibuprofen tablet with a weight equivalent amount of locust bean gum, wherein the ratio of said xanthan gum to said locust bean gum ranges from about 1:20 to about 20:1, said tablet providing effective blood plasma levels of said ibuprofen.

Claim 27. (Currently Amended) A sustained release ibuprofen tablet comprising from about 600mg to about 1000 mg ibuprofen; xanthan gum; locust bean gum; and an inert diluent; wherein the combined weight ~~of~~ of said xanthan gum and said locust bean gum is from about 7 to about 40 percent by weight of ~~th~~ the final tablet weight and the ratio of ibuprofen to the combined weight of said xanthan gum and said locust bean gum is from about 1:0.06 to about 1:0.4, said tablet providing effective blood plasma levels of said ibuprofen.

Claim 28. (Previously Presented) The sustained release ibuprofen tablet of claim 27, wherein the ratio of ibuprofen to the combined weight of said xanthan gum and locust bean gum is from about 1:0.08 to about 1:0.25.